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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Jones et al.

Serial No.: 10/644,256

Filed: August 20, 2003

For: EFFICIENT PRODUCTION OF IgA
IN RECOMBINANT MAMMALIAN
CELLS

Confirmation No.: 6153

Examiner: W. Schlapkohl, Ph.D.

Group Art Unit: 1632

Attorney Docket No.: 2578-6077US

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record.

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
US - 5,192,539	03-09-1993	Van Der Marel et al.
US - 6,878,549 B1	04-12-2005	Vogels et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
EP 0 833 934 B1	04-08-1998	Fallaux et al.
WO 99/24068	05-20-1999	Michigan State University

Other Documents

ALKHATIB et al., "Expression of Bicistronic Measles Virus P/C mRNA by Using Hybrid Adenovirus: Levels of C Protein Synthesized In Vivo Are Unaffected by the Presence or Absence of the Upstream P Initiator Codon," Journal of Virology, November 1988, pp. 4059-4068, Vol. 62, No. 11.

ALKHATIB et al., "High-Level Eucaryotic In Vivo Expression of Biologically Active Measles Virus Hemagglutinin by Using an Adenovirus Type 5 Helper-Free Vector System," Journal of Virology, August 1988, pp. 2718-2727, Vol. 62, No. 8.

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CARAVOKYRI et al., "Constitutive Episomal Expression of Polypeptide IX (pIX) in a 293-Based Cell Line Complements that Deficiency of pIX Mutant Adenovirus Type 5," *Journal of Virology*, November 1995, pp. 6627-6633, Vol. 69, No. 11.

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COTE et al., Serum-Free Production of Recombinant Proteins and Adenoviral Vectors by 293SF-3F6 Cells, *Biotechnology and Bioengineering*, September 5, 1998, pp. 567-75, Vol. 59, No. 5.

DuBRIDGE et al., "Analysis of Mutation in Human Cells by Using an Epstein-Barr Virus Shuttle System," *Molecular and Cellular Biology*, January 1987, pp. 397-387, Vol. 7, No. 1.

ENDO et al., Growth of Influenza A Virus in Primary, Differentiated Epithelial Cells Derived from Adenoids, *Journal of Virology*, Mar. 1996, pp. 2055-58, Vol. 70, No. 3.

FALLAUX et al., Characterization of 911: A New Helper Cell Line for the Titration and Propagation of Early Region 1-Deleted Adenoviral Vectors, *Human Gene Therapy*, January 20, 1996, pp. 215-222, Vol. 7.

Figure 1 submitted by Opponent I.

GALLIMORE et al., Transformation of Human Embryo Retinoblasts with Simian Virus 40, Adenovirus and ras Oncogenes, *Anticancer Research*, 1986, pp. 499-508, Vol.6.

GARNIER et al., Scale-up of the adenovirus expression system for the production of recombinant protein in human 293S cells, *Cytotechnology*, 1994, pp. 145-55, Vol. 15.

GenBank Accession No. X02996.1, 1993, "Adenovirus type 5 left 32% of the genome."

GIBCO cell culture, A Guide to Serum-Free Cell Culture, www.invitrogen.com.

GRAHAM et al., "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5," *J. Gen. Virol.*, 1997, pp. 59-72, Vol. 36.

GRAHAM et al., "Growth of 293 cells in suspension culture," *J Gen Virol*, March 1987, pp. 937-940, Vol. 68.

GRAHAM, Cell Lines, Promochem (visited 04.10.2005) <<http://www.lgcpromochem-atcc.com/SearchCatalogs/longview.cfm?view=ce,1146678...>>.

HOLZER et al., "Construction of a Vaccinia Virus Deficient in the Essential DNA Repair Enzyme Uracil DNA Glycosylase by a Complementing Cell Line," Journal of Virology, July 1997, pp. 4997-5002, Vol. 71, No. 7.

INOUE et al., Production of Recombinant Human Monoclonal Antibody Using ras-Amplified BHK-21 Cells in a Protein-free Medium, Biosci. Biotech. Biochem., 1996, pp. 811-17, Vol. 60, No. 5.

Interlocutory Decision of the Opposition Division of 21 July 2003 in the case EP 0 695 351(European application 94 913 174.2)

LOPEZ et al., Efficient production of biologically active human recombinant proteins in human lymphoblastoid cells form integrative and episomal expression vectors, Gene, 1994, pp. 285-91, Vol. 148.

LUTZ et al., "The Product of the Adenovirus Intermediate Gene IX Is a Transcriptional Activator," Journal of Virology, July 1997, pp. 5102-5109, Vol. 71, No. 7.

MANSEVIGI et al., "Protection from Herpes Simplex Virus Type 1 Lethal and Latent Infections by Secreted Recombinant Glycoprotein B Constitutively Expressed in Human Cells with a BK Virus Episomal Vector," Journal of Virology, January 1990, pp. 431-436, Vol. 64, No.1.

Marketing Authorization and Scientific Discussion for Xigris.

MASSIE et al., Improved Adenovirus Vector Provides Herpes Simplex Virus Ribonucleotide Reductase R1 and R2 Subunits Very Efficiently, Biotechnology, June 1995, pp. 602-08, Vol. 13.

MERTEN et al., Production of Influenza Virus in Cell Cultures for Vaccine Preparation, Exp Med Biol., 1996, pp. 141-51, Vol. 397.

NEUMANN et al., "Generation of influenza A viruses entirely from cloned cDNAs," Proc. Natl. Acad. Sci., August 1999, pp. 9345-9350, Vol. 96.

Notice of Opposition to a European Patent for 1 161 548 by Serono.

Opposition against European patent 1 108 878 B1 filed October 5, 2005 in the name and on behalf of CEVEC Pharmaceuticals GmbH.

Opposition against European patent 1 161 548 B1 filed November 16, 2005, in the name and on behalf of CEVEC Pharmaceutical GmbH.

Opposition against European patent 1108787 filed October 5, 2005 in the name and on behalf of Probiogen AG.

ORY et al., "A stable human-derived packaging cell line for production of high titer retrovirus/vesicular stomatitis virus G pseudotypes," Proc. Natl. Acad. Sci., October 1996, pp. 11400-11406, Vol. 93.

PARKINSON et al., "Stable Expression of a Secretable Deletion Mutant of Recombinant Human Thrombomodulin in Mammalian Cells," The Journal of Biological Chemistry," 25 July 1990, pp. 12602-12610, Vol. 265, No. 21.

PAUL et al., Increased Viral Titer Through Concentration of Viral Harvests from Retroviral Packaging Lines, Human Gene Therapy, 1993, pp. 609-15, Vol. 4.

PLESCHKA et al., "A Plasmid-Based Reverse Genetics System for Influenza A Virus," Journal of Virology, June 1996, pp. 4188-4192, Vol. 70, No. 6.

PubMed listing of abstracts (visited 04.10.2005)
<<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?CMD=search&DB=pubmed>.

REINA et al., Comparison of Madin-Darby Canine Kidney cells (MDCK) with a Green Monkey Continuous Cell Line (Vero) and Human Lung Embryonated Cells (MRC-5) in the Isolation of Influenza A Virus from Nasopharyngeal Aspirates by Shell Vial Culture, Journal of Clinical Microbiology, July 1997, pp. 1900-01, Vol. 35, No. 7.

RHIM et al., "Development of Human Cell Lines from Multiple Organs," Annals of the New York Academy of Sciences, 2000, pp. 16-25, Vol. 919.

SPECTOR et al., "Regulation of Integrated Adenovirus Sequences During Adenovirus Infection of Transformed Cells," Journal of Virology, December 1980, pp. 860-871, Vol. 36, No. 3.

STEVENS et al., "The N-Terminal Extension of the Influenza B Virus Nucleoprotein Is Not Required for Nuclear Accumulation or the Expression and Replication of a Model RNA," Journal of Virology, June 1998, pp. 5307-5312, Vol. 72, No. 6.

U.S. Department of Health and Human Services, Public Health Service, Food and drug Administration, Center for Biologics Evaluation and Research, International Association for Biologicals, National Institute of Allergy and Infectious Diseases, National Vaccine Program Office, World Health Organization, Evolving Scientific and Regulatory Perspectives on Cell Substrates for Vaccine Development, Workshop, Friday, 10 September 1999 (visited 30.09.2005) <<http://www.fda.gov/cber/minutes/0910evolv.txt>>.

YAN et al., Novel Asn-linked oligosaccharides terminating in GalNAcbeta(1-4)[Fucalpha(1-3)]GlcNAcbeta(1-) are present in recombinant human Protein C expressed in human kidney 293 cells, Glycobiology, 1993, pp. 597-608, Vol. 3. No. 6.

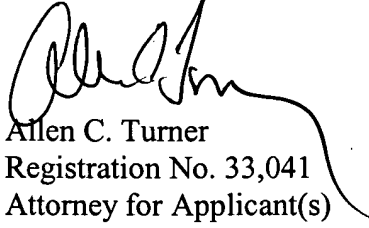
YEAGER et al., Constructing immortalized human cell lines, Current Opinion Biotechnology, 1999, pp. 465-69, Vol. 10.

YEH et al., Adenoviral Vectors, pp. 25-42 of "Concepts in Gene Therapy," Publisher: Walter de Gruyter, New York.

This Information Disclosure Statement is believed to be filed before the mailing date of a first Office Action on the merits; therefore, no fee is due.

Serial No.: 10/644,256

Respectfully submitted,



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Application Number	10/644,256
Filing Date	August 20, 2003
First Named Inventor	Jones et al.
Group Art Unit	1632
Examiner Name	W. Schlapkohl, Ph.D.
Attorney Docket Number	2578-6077US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		ALKHATIB et al., "Expression of Bicistronic Measles Virus P/C mRNA by Using Hybrid Adenovirus: Levels of C Protein Synthesized In Vivo Are Unaffected by the Presence or Absence of the Upstream P Initiator Codon," Journal of Virology, November 1988, pp. 4059-4068, Vol. 62, No. 11.	
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		COTE et al., Serum-Free Production of Recombinant Proteins and Adenoviral Vectors by 293SF-3F6 Cells, Biotechnology and Bioengineering, September 5, 1998, pp. 567-75, Vol. 59, No. 5.	
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		FALLAUX et al., Characterization of 911: A New Helper Cell Line for the Titration and Propagation of Early Region 1- Deleted Adenoviral Vectors, Human Gene Therapy, January 20, 1996, pp. 215-222, Vol. 7.	

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		Figure 1 submitted by Opponent I.	
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		GARNIER et al., Scale-up of the adenovirus expression system for the production of recombinant protein in human 293S cells, Cytotechnology, 1994, pp. 145-55, Vol. 15.	
		GenBank Accession No. X02996.1, 1993, "Adenovirus type 5 left 32% of the genome."	
		GIBCO cell culture, A Guide to Serum-Free Cell Culture, www.invitrogen.com.	
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		GRAHAM et al., "Growth of 293 cells in suspension culture," J Gen Virol, March 1987, pp. 937-940, Vol. 68.	
		GRAHAM, Cell Lines, Promochem (visited 04.10.2005) < http://www.lgcpromochem-atcc.com/SearchCatalogs/longview.cfm?view=ce,1146678... >.	
		HOLZER et al., "Construction of a Vaccinia Virus Deficient in the Essential DNA Repair Enzyme Uracil DNA Glycosylase by a Complementing Cell Line," Journal of Virology, July 1997, pp. 4997-5002, Vol. 71, No. 7.	
		INOUE et al., Production of Recombinant Human Monoclonal Antibody Using ras-Amplified BHK-21 Cells in a Protein-free Medium, Biosci. Biotech. Biochem., 1996, pp. 811-17, Vol. 60, No. 5.	
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		MANSERVIGI et al., "Protection from Herpes Simplex Virus Type 1 Lethal and Latent Infections by Secreted Recombinant Glycoprotein B Constitutively Expressed in Human Cells with a BK Virus Episomal Vector," Journal of Virology, January 1990, pp. 431-436, Vol. 64, No.1.	
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		PAUL et al., Increased Viral Titer Through Concentration of Viral Harvests from Retroviral Packaging Lines, Human Gene Therapy, 1993, pp. 609-15, Vol. 4.	
		PLESCHKA et al., "A Plasmid-Based Reverse Genetics System for Influenza A Virus," Journal of Virology, June 1996, pp. 4188-4192, Vol. 70, No. 6.	
		PubMed listing of abstracts (visited 04.10.2005) < http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?CMD=search&DB=pubmed >.	
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		SPECTOR et al., "Regulation of Integrated Adenovirus Sequences During Adenovirus Infection of Transformed Cells," Journal of Virology, December 1980, pp. 860-871, Vol. 36, No. 3.	
		STEVENS et al., "The N-Terminal Extension of the Influenza B Virus Nucleoprotein Is Not Required for Nuclear Accumulation or the Expression and Replication of a Model RNA," Journal of Virology, June 1998, pp. 5307-5312, Vol. 72, No. 6.	
		U.S. Department of Health and Human Services, Public Health Service, Food and drug Administration, Center for Biologics Evaluation and Research, International Association for Biologicals, National Institute of Allergy and Infectious Diseases, National Vaccine Program Office, World Health Organization, Evolving Scientific and Regulatory Perspectives on Cell Substrates for Vaccine Development, Workshop, Friday, 10 September 1999 (visited 30.09.2005) < http://www.fda.gov/cber/minutes/0910evolvt.txt >.	
		YAN et al., Novel Asn-linked oligosaccharides terminating in GalNAc(1-4)[Fuc(1-3)]GlcNAc(1-2) are present in recombinant human Protein C expressed in human kidney 293 cells, Glycobiology, 1993, pp. 597-608, Vol. 3, No. 6.	
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